

9/18/97  
D1245B



# U.S. FOOD AND DRUG ADMINISTRATION

NEW YORK DISTRICT  
850 THIRD AVENUE, BROOKLYN, NEW YORK 11232

HFI 35

Telephone: [718] 965-5300

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

MAR 7 1997

## WARNING LETTER

Mr. Dane Neller, President  
Dean & DeLuca  
560 Broadway  
New York, NY 10012

Ref: 32-NYK-97

Dear Mr. Neller:

The Food and Drug Administration has information which shows that your firm has violated the Federal Food, Drug and Cosmetic Act (The Act).

The Food and Drug Administration recently attempted to collect a sample of smoked salmon, which your firm offered for entry into the United States through the Port of New York/New Jersey under entry number D053020392-9 dated December 9, 1996.

Our attempt to collect the sample of smoked salmon revealed that your firm distributed the entire shipment without suitable clearance from FDA. The failure to hold a shipment intact pending receipt of a May Proceed or Release Notice from FDA is a violation of the Federal Food, Drug and Cosmetic Act. We are thereby requesting U.S. Customs to order redelivery of this shipment (copy enclosed).

Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction, or detention without physical examination, to ensure that imported product is held intact until released by FDA.

Page 2

Mr. Dane Neller  
Dean & DeLuca

Within 15 working days of receipt of this letter, please notify this office in writing of the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent the reoccurrence of the violation.

Your response should be directed to Ms. Mildred Harris, Compliance Officer, Food and Drug Administration, 850 Third Avenue, Brooklyn, NY 11232.

A copy of this letter, except for any confidential, personal or commercial information will be placed on public display at this office no earlier than fifteen (15) days after the date of this letter. Your response will also be on public display with only confidential, personal or commercial information purged.

Sincerely,

A handwritten signature in cursive script, appearing to read "Diana Amador".

Diana Amador  
Acting District Director

Enc.